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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/229,229	01/12/1999	GEOFFREY M. WAHL		7340

7590 12/16/2003

Cathryn Campbell
McDermott Will & Emery
7th Floor
4370 La Jolla Village Drive
San Diego, CA 92122

EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

35

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/229,229

Applicant(s)

WAHL ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-27, 31-50, 53 and 54 is/are pending in the application.
- 4a) Of the above claim(s) 5-27, 31 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-50, 53 and 54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed 9/10/2003 is acknowledged.

2. Claims 5-27, 31-50, 53 and 54 are pending.

Claims 5-27, 31, and 32, drawn to non-elected inventions, are withdrawn from consideration.

Claims 33-50, 53 and 54 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

4. The rejection of claim 39 under 112, 2nd paragraph is withdrawn upon further consideration.

Claim Rejections Maintained and New Grounds of Rejection:

5. The rejection of claims 33-38, 42-50, 53 and 54 under 35 U.S.C. 103(a) as being unpatentable over Robinett (Journal of Cell Biology (1996) 135(6): 1685-1700) in view of Abken (Cancer Journal (1995) 8(3): 94-102) is maintained for the reasons of record.

Applicant's arguments have been carefully considered, but are unpersuasive. Applicant argues that prior art does not suggest the claimed inventions, and that there is no motivation to

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combine the teachings of the prior art, and that neither reference suggests methods for screening of agents that increase or decrease the amount of double minute chromosomes or extrachromosomal DNA. This argument is not found persuasive, because Abken teaches that extrachromosomal DNA and double minute DNA is chromosomal in origin and that double minute DNA can be eliminated from cancer cells by micronuclei formation in response to administration of various drugs. Abken also teaches that extrachromosomal DNA such as double minute DNA contains extra copies of oncogenes, which may cause the growth dysregulation of cancer cells. Furthermore, Abken teaches an examples of agents that induces micronuclei formation and the reduction of double minute chromosomes (DM), hydroxyurea, inhibitors of poly(ADP-ribose)polymerase, and dimethyl sulfoxide, and suggests that analyses of the stability of extrachromosomal DNA molecules provides a rational basis for design of innovative therapeutic strategies (see page 99, 1st col.). Thus, Abken provides the teachings that suggest methods for screening for such agents because Abken teaches that such agents have already been discovered and that such agents result in differentiation of tumor cells, and that such agents may be the basis for a therapeutic strategies.

The motivation to combine the teachings of Robinett with Abken is that Robinett teaches methods for visualizing chromosomes, and therefore provides a method for visualizing extrachromosomal DNA or double minute DNA, which methods could be used in methods to determine if an agent were increasing or decreasing the amount of extrachromosomal DNA or double minute DNA.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art to use the technique of chromosome visualization taught by Robinett to make a method for

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identifying other agents that induce micronuclei formation and thereby decrease the amount of double minute chromosomes. Alternatively, because the presence of double minutes is associated with carcinogenesis, it would be *prima facie* obvious to use the technique of Robinett to identify agents that increase the amount of double minute DNA or extrachromosomal DNA.

6. Claims 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the description in the specification of the genus of histones is not representative of the genus of histone analogues. Therefore, the genus of histone analogs is not adequately described such that one of skill in the art would understand that applicant was in possession of the claimed methods, because the claimed methods read on methods using histone analogs.

If a product to be used in a claimed method is not adequately described, then the claimed method is not adequately described. In the instant case the claimed methods are drawn in part to methods comprising the use of histone analogs. The specification confines its description to methods using histone molecules, but fails to provide a definition or description of what constitutes or how to make a histone analog. Applicants appear to argue that histone analogues are confined to those molecules that comprise amino acid analogues, and argue that amino acid analogs are known in the art. However, the specification fails to define histone analogues as proteins made up of amino acid analogues, and fails to provide any examples by way of

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providing an exemplary structure of a histone analogue that functions as required in the claimed method and is comprised of amino acid analogues. Therefore, it does not appear that applicant was in possession of the claimed inventions to the extent the inventions read on methods comprising the use of histone analogues.

Conclusion


No claim is allowed. Claims 33-50, 53 and 54 are rejected.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
December 14, 2003


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY